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To Whom It May Concern

I have had years to mull over many of the proposed changes to the federal drug testing program as I have attended DTAB meetings on the subject of alternative matrices. Having been in "NIDA" testing for fourteen years, I have seen virtually all of the changes to the program since its inception. Most of these changes have been positive, seeking to better the forensic acceptability of testing procedures and strengthen the program against litigation, while changing cutoff levels to better identify drug users. The proposed changes and additions to the current program, however, I feel do not strengthen the program, but leave it vulnerable to many more challenges. Allow me to address these individually:

Alternative Matrices

Allowing a choice of alternative matrices allows a choice of detection times. It is unfair to federal and DOT regulated employees to treat them differently from one another. This also allows the possibility of conflicting results between matrices and more litigation.

Hair

The words "Racial Bias" is more than enough to destroy the program alone without even digging into the many problems that hair testing has analytically. Although some experts point out that this is more correctly a hair type bias, statistically it is still race bias. Hair testing, however, has many more problems such as the lack of peer review. The recent rounds of proficiency tests in the United States and those done in Europe show that there is poor agreement between hair testing labs as to the detection and quantification of drugs in hair. This is furthered by the lack of communication between the labs because of proprietary methods of testing. The question of referee testing, thus, becomes an issue. Further, there are external contamination issues with hair despite what some of the labs contend. Besides, the easiest way to foil hair testing is to wear an extremely short hairstyle or to shave your head.

Oral Fluid

The inability of oral fluid to detect the use of marijuana should exclude it from consideration as a viable testing matrix. Requiring a urine sample for this purpose is both impractical and costly. Also, the detection periods for oral fluid are too short and would result in a decrease in drug user identification.

Sweat

Sweat testing suffers from some of the problems that plagues hair testing. For

example, peer review in sweat testing is nonexistent since only one lab has been commercially testing sweat. External contamination is another issue. At one of the first DTAB meetings, representatives for sweat testing illustrated the need to normalize controls due to their bias in testing. Meaning, controls don't read like patients because of the method of spiking the patches with drugs. Hair has a similar problem of introducing drugs into the matrix. There are also problems concerning sweat patch duplication as a means of adulteration.

Point of Collection Testing Devices

POCT's have come along way since their introduction. Many of them use the same antibodies as the immunoassays used by urine testing laboratories currently in the program. However, allowing the collection site autonomy over the screening of samples is easily corruptible. At an NLCP workshop, I asked the question to NLCP and SAMHSA staff, "Who in the program do you trust the least and who do you trust the most?" The answer echoed by all was the collection site and the laboratories respectively. The response I gave then, I give now. Why would you take testing away from the most trusted and give it to the least trusted? Corruption is currently something that is commonplace at collection facilities, allowing urine substitutions, adulterations and negative results for those already using POCT's for a fee. A hundred dollars is a small fee to someone needing to pass a test for a job potentially worth 60-80K a year. POCT's are still too easy to adulterate without detection and still have too many false negatives to be fully trusted. As a reseller of these devices, I have become increasingly aware of the effects of storage on the performance of the device. This is a huge problem with regards to shipping and testing in remote areas.

Initial Testing Facilities (IITF)

IITF's have the same problems as POCT's when it comes to corruptibility, especially if it is company operated. However, I believe this type of lab will prove too costly for operation in this context. I believe IITF's will become a weak link in the testing chain in regards to chain of custody and expert testimony. In addition, the proposed regulations are requiring additions to adulteration testing such as four place digital refractometers for specific gravity testing and oxidant testing. All current and proposed validity testing rules should be required of IITF's as well since all of the required validity testing happens during the initial testing phase. I am only mentioning urine at this point, IITF's for the alternate matrices will introduce many more and complicated issues. Then, there are questions of reporting, statistical reports, confidentiality, etc. I feel for the TPA/MRO's who will be left to sort out the mess of who tested where and how.

Validity Testing

I understand the change in the creatinine cutoff for substitution from 5.0 mg/dL to 2.0 mg/dL, but I cannot understand the requirement of four decimal places for

specific gravity on these samples. First, requiring labs to purchase a $9000 dollar instrument to test far less than 1% of the samples is unreasonable. Many of the labs were using three place digital refractometers to remove the human element from specific gravity measurements. These labs now have to purchase a new and more costly instrument to test only a few specimens. For the large labs, this is small change, but for small labs, this is a huge unjustifiable cost for what I call "splitting hairs". Secondly, I question whether the fourth decimal place is necessary. The rules written for three places should be sufficient. Legal manipulation may not stop at four places, where does it end? I have similar problems with requiring a test for oxidants. This is no big deal to large labs, but to small labs trying to compete, all new testing becomes value-added and eats away at the bottom line. This is especially a problem since the oxidant assay does not give any new information for adulterants that cannot already be seen from the immunoassay results. Although there are oxidants out there that do not show immunoassay interference, they also do not show reactivity to the oxidant assay. We are going to report immunoassay interference as "invalid" anyway, we should not be forced to use another test (and subsequent retest) to report the same result. I am, however, grateful that the proposed regulations are not requiring a separate confirmation test(s) at this time. But as with specific gravity, I know the day is coming when I will be required to confirm for adulterants with a second analytical technique. This will break the backs of small labs and add more complications to an already complicated program.

Proposed Drug Changes

I have no objections to the additions of MDA, MDEA, and MDMA to the amphetamine panel. Most labs already test for them and 250 ng/mL is a reasonable cutoff. However, it is not necessary to use two different screen tests for the detection of these drugs. There are screen reagents that are more sensitive for these drugs that can be calibrated with methamphetamine and behave according to NLCP program guidance. Someone needs to do their homework here and talk to the labs currently using these products. Their detection dynamics for the new drugs are no different than the current dynamics between amphetamine and methamphetamine detection by standard amphetamine initial tests. Adding a second immunoassay will be costly without cause. The reagent companies should be consulted, but keep in mind they want to sell more reagent and may be biased. I asked one company if they were going to respond to this and I was told that they most likely would not respond (at least favorably to the labs). Dropping the cutoff to 500 ng/mL on the initial tests should also be revisited. I already have customers that require this and they have no more confirmed positives (@250 ng/mL) than compared to a 1000 ng/mL screen cutoff. They do, however, have many more nonconfirms, i.e. false positive screens.

Conclusion

I am not adverse to doing things differently with the federal drug testing program, but I feel any additions in facilities or matrices should live up to the current scope that exists in urine testing. That is, they should be fair and unbiased to the employee, they should detect all drugs in one sample, they should require peer review, they should require the same level of validity testing and they should not be easily corrupted. I believe the program should move forward and answer the questions at hand before proceeding to rules additions and changes. Each of these issues needs to be resolved item (matrix) by item prior to admission into the program. Radical change to the federal program will affect the DOT program and subsequently all other programs and will result in damage to the labs that currently make up its backbone. Thank you for your consideration.

Respectfully
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